K012987

NOV 0 7 2001

pHoenix Diagnostics, Inc.
8 TECH CIRCLE • NATICK, MA 01760 • TEL: 508-655-8310 • FAX: 508-655-8273

510 K SUMMARY

1. ***Submitter:*** Ram Nunna

   Address: pHoenix Diagnostics Inc.
   8 Tech Circle
   Natick. MA 01760

   Phone: 508-655-8310

   Fax: 508-655-8273

   Contact Person: Ram Nunna

   Date of Summary: 11/01/01

2. ***Device Name and Associated Information:***

   Device Name: Electrolyte Calibration Set for Medica Easylyte Calcium Analyzer.

   Trade Name: Same as above.

   Common Name: Same as above.

   Classification and Associated Information:

   Classification: Calibrator, Multianalyte Mixture

   Device Classification: II

   Panel: Chemistry 75

   Product Code: JIX

3. ***pHoenix Electrolyte Calibration Set is similar in composition and performance to the following systems calibration set:***

   1. Medica Easylyte Electrolyte Analyzer.
   2. Nova Biomedical Electrolyte Analyzer.

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Attachment: Substantial equivalence comparison.

4. ***510 K Summary:*** Phoenix Electrolyte Calibration Set for Medica Easylyte Analyzer consists of two standards A and B for use in calibrating Na^+, K^+, Ca^{++} and pH electrodes. The Medica Easylyte Calcium Analyzer measures Na^+, K^+, Ca^{++}, and pH using ion selective electrode technology. pHoenix calibration set is intended to serve as direct replacement to similar calibrator manufactured by Medica Corporation. pHoenix uses similar composition, description and packaging design as that used by Medica Corporation in its calibration set. pHoenix has shown performance equivalence of its calibration set, to Medica Corporation calibration set, in the following manner:

    1. through a method comparison
    2. through a precision study

5. ***Intended use:***

    pHoenix Electrolyte Calibration Set for Medica Easylyte Calcium analyzer is intended to calibrate Na, K, Ca^{++}, pH electrodes of Medica Easylyte Calcium analyzer.

Date: 11/5/01

Signature:

Ram Nunna
President,
pHoenix Diagnostics Inc.

Email: tmccarthy@phoenixdiagnostics.com • Web: www.phoenixdiagnostics.com

Substantial Equivalence Comparison

Predicate Device Name: Standard A and Standard B for Medica EasyLyte Calcium Analyzer
510 (k) Number: K943091

The pHoenix products under application are similar in composition and function to the Medica products as stated above. A summary of comparison between the Medica Corporation and pHoenix products is as follows:

Areas	Comparison of pHoenix and Medica products	Comments
Intended use	Similar	Both are intended for the calibration of Na, K, Ca and pH for the Medica EasyLyte Calcium Analyzer
Target population	Similar	Medica EasyLyte Calcium Analyzer
Design and material	Similar	Contains Sodium, Potassium, Calcium and buffers in an aqueous base
Performance	Similar	See 510(k) Summary
Sterility	Similar	No Growth
Biocompatibility	Similar	Not Applicable
Mechanical Safety	Similar	Not Applicable
Chemical Safety	Similar	Both contains no hazardous chemicals
Human Factors	Similar	Not Applicable
Energy used	Similar	Not Applicable
Compatibility with environment and other devices	Similar	Not Applicable
Where use?	Similar	Laboratories
Standards	Similar	No known standards
Electrical, thermal and radiation safety	Similar	Not Applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 0 7 2001

Mr. Ram Nunna
President
pHoenix Diagnostic Inc.
8 Tech Circle
Natick, MA 01760

Re: k012987
Trade/Device Name: pHoenix Electrolyte Calibration Set for the Medica EasyLyte Calcium Analyzer
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: September 6, 2001
Received: September 6, 2001

Dear Mr. Nunna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012987

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 012987

Device Name: pHoenix Electrolyte Calibration Set for the Medica EasyLyte Calcium Analyzer

Indications For Use:

Intended Use:

The pHoenix Electrolyte Calibrator Set for the Medica EasyLyte Calcium Analyzer is intended for use as calibrators to calibrate Na^+, K^+, Ca^+ and pH for the Medica EasyLyte Calcium Analyzer.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Labor
510(k) Number K012987